





PRIORITY

The Patent Office Concept House Cardiff Road Newport South Wales NP10 8QQ

REC'D 2 1 AUG 2003

WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before reregistration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

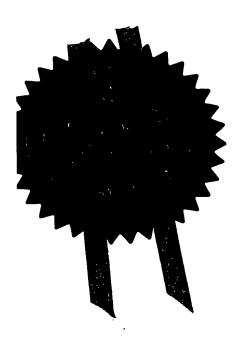
In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated

15 July 2003



tents Form 1/77

Patents Act 1977 (Rule 16)



2 2 JUN 2002



The Patent Office

Request for grant of \a\parent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form) 22 JUN 2002

Cardiff Road Newport Gwent NP9 1RH

you fill in this form) 1. Your reference 6/SG/12755 Patent application number n214452.5 (The Patent Office will fill in this part) 3. Full name, address and postcode of the or of Barry Peter LIVERSIDGE, each applicant (underline all surnames) The Wick, Wick Road, Langham, Colchester, Essex CO4 5PE. Patents ADP number (if you know it) 7774219001 If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

MEDICAL NEEDLE ASSEMBLIES

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including postcode)

Patents ADP number (if you know it)

Sanderson & Co.

34 East Stockwell Street Colchester Essex CO1 1ST

1446001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

No

Priority application number (if you know it)

Date of filing (day/month/year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing (day/month/year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if: ---

request? (Answer 'Yes' if: - - - a) any applicant named in part 3 is not an inventor, or

b) there is an inventor who is not named as an applicant, or

c) any named applicant is a corporate body.

See note (d))

Patents Form 1/77

Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description

Claim(s)

Abstract

None

Drawing(s)

10 +10

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right

None

to grant of a patent (Patents Form 7/77)

None

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination

None

(Patents Form 10/77)

Any other documents

(Please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Sanderson & Co -

Agents for the Applicant

June, 2002

Date

Name and daytime telephone number of 12.

person to contact in the United Kingdom

Francis Gillam

01206 571187

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505. a)
- Write your answers in capital letters using black ink or you may type them. b)
- If there is not enough space for all the relevant details on any part of this from, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed. d)
- Once you have filled in the form you must remember to sign and date it. e)
- For details of the fee and ways to pay please contact the Patent Office.

MEDICAL NEEDLE ASSEMBLIES

- This invention relates to an assembly for supporting a medical needle having a mount end and a sharp tip, intended for penetration of a human or animal body or other medical uses such as penetration of a pierceable membrane of an intravenous medication system. The invention further relates to such an assembly including a medical needle, ready for penetration as aforesaid. In the following, all such medical uses will be described simply with reference to the penetration of a body.

Fluids of various kinds may be administered to a human or animal body by means of a hollow needle in conjunction with a source of the required fluid. For example, such a needle may be used in conjunction with a syringe holding a liquid drug, the needle being used to penetrate the skin being used to penetrate the body to the site at which the drug is to be received. Equally, body fluids may be withdrawn by using a hollow needle which is used to penetrate the body until the tip is located at the site from which fluid is to be withdrawn.

A recognised hazard for clinicians and other persons using medical needles for the above described purposes is the risk of a so-called needle-stick injury - that is to say the accidental penetration of the clinician's skin by the needle. Prior to the use of the needle to supply a fluid to or to withdraw fluid from a body, this rarely presents much of a problem, though once the needle has been used on a body, there is a very much higher risk of a serious consequence for the clinician. During use of the needle to penetrate the body tissues of a patient, the needle is likely to become contaminated with various organisms and should a needle-stick injury occur, these could infect the clinician.

25

5

10

There have been numerous proposals for protecting the sharp tip of a used needle, in order to reduce the risk of a needle-stick injury following use of the needle. Some proposals have actually increased the likelihood of such an injury by virtue of the action which must be performed to protect the tip, even if the risk thereafter is lessened. Despite all of the proposals which have previously been made, very few have achieved commercial success, nor has there been wide acceptance by the medical industry. Many proposals are somewhat complex and involve a significantly greater manufacturing cost, and so are unacceptable on economic grounds. Others are much more difficult to use as compared to an unprotected needle, and so are rejected by clinicians. Yet further proposals do not allow compliance with best practice protocols.

There is a significant demand for a protective device which, when used with a needle, allows a clinician to use the needle in much the same way as the clinician already uses an unprotected needle, but which can be manufactured economically and which provides a high degree of protection against needle-stick injury. In this connection, it is highly preferred that the device operates fully automatically, without intervention by the clinician, to give a degree of protection to the needle tip before use, and after use wholly prevents access to the needle tip other than by a determined attempt to override the protection. In this way, protection may be afforded not just to the clinician, but also to others who could come-into-a risky situation with used needles, such as waste disposal operators, cleaners, and so on.

According to one aspect of the present invention, there is provided a medical needle assembly comprising:

- a needle having a mount end and a sharp tip;

10

15

20

- a support wall carrying the mount end of a needle so as to project
 away therefrom;
 - a sleeve mounted on the support wall and being slidable with respect thereto from an initial position where the sleeve covers at least the greater part of the projecting needle to a retracted position where the tip of the needle is exposed along with a part of the needle extending back from the tip, and then to a protecting position where the sleeve covers the needle tip and at least part of the needle projecting back from its tip;
 - a spring arranged to urge the sleeve away from the support wall;
 - a locking member projecting forwardly from the support wall, the locking member being movable between a free position where the locking member extends generally parallel to the needle axis and the sleeve may slide to its withdrawn position and a blocking position where the locking member is disposed between the support wall and the sleeve and is off-axis with respect to the needle axis, thereby blocking movement of the sleeve away from its initial position; and
 - control means which holds the locking member in its free position until tripped by movement of the sleeve away from its initial position, the control means thereafter permitting the locking member to move to its blocking position on movement of the sleeve to its protecting position, so preventing subsequent movement of the sleeve away from its protecting position.

The support wall may define a connector for a cylindrical body such as a syringe, to extend co-axially with the needle. In one embodiment, the tubular body may serve slidably to support the sleeve when the wall has been connected to the body. Alternatively, the support wall may be defined by a rear wall of the tubular housing on or within which the sleeve is slidably carried.

The control means may include a releasable connection between two components which are relatively movable along the needle axis, such that sufficient force releases the connection and then allows the locking member to move to its blocking position, when the sleeve has moved to its protecting position. In a preferred embodiment, there is provided a control member mounted within the sleeve and the releasable connection is formed between the sleeve and the control member. In another embodiment, the releasable connection is formed between the housing and the locking member, movement of the sleeve towards its retracted position releasing that connection to permit the locking member to move towards the support wall, thereafter to perform the blocking action on movement of the sleeve to its protecting position.

10

15

20

In accordance with a second aspect of the present invention, there is provided an assembly for supporting a medical needle having a mount end and a tip, which assembly comprises:

 a tubular housing having a rear wall provided with an internal mount portion adapted to support the mount end of a needle, the housing being open at its opposed end so that a supported needle may extend from the mount portion and project out of the opposed end; - a sleeve slidably mounted within the housing to surround a supported needle, the sleeve being slidable with respect to the housing from an initial position where the sleeve will cover at least the greater part of a supported needle projecting from the housing to a retracted position exposing the tip and part of a supported needle extending back from the tip, and then to a protecting position where the sleeve covers that part of the needle projecting beyond the housing including the needle tip, the sleeve having a rear end nearer the rear wall of the housing and there being means to prevent the sleeve sliding off the housing;

- a locking member provided within the housing, the locking member having a base disposed between the rear end of the sleeve and the rear wall of the housing and a locking section which extends from the base generally parallel to the length of the sleeve and co-operable with the sleeve;

– a control member also receivable within the sleeve and which initially supports the locking section of the locking member to lie substantially parallel to the sleeve axis, there being a releasable connection between the sleeve and the control member; and

 a spring disposed to urge apart the sleeve and the locking member;

in which assembly:

10

15

20

- with the sleeve in its initial position the control member is disposed adjacent the rear end of the sleeve, engaged with the locking section of the locking member;
- on movement of the sleeve to its retracted position the control
 member releasable connection is released so permitting the

control member to move into the sleeve, the control member

guiding the locking section into the sleeve; and

5

10

15

20

25

- on the sleeve subsequently moving to its protecting position under the action of the spring, the base of the locking member is urged to bear on the housing rear wall and the locking section of the locking member engages behind the rear end of the sleeve, so preventing subsequent retraction of the sleeve from its protecting position.

According to a third aspect of this invention, there is provided an assembly as described above, in combination with a medical needle having a mount end and a tip, the mount end of the needle being supported by the mount portion of the housing, to extend from that mount portion through and beyond the housing, the needle also extending through the locking member, the control member and the sleeve.

With the arrangements of the present invention, a needle is initially protected at least to some extent, though preferably wholly, by the sleeve, which extends from the assembly housing to overlie at least the greater part of the needle projecting from the housing. The control member serves to hold the locking member in such a position that the sleeve may be moved with light pressure on its tip to a retracted position, where that part of the needle projecting beyond the housing is exposed. pressure may be exerted by the skin of a patient or the pierceable membrane of a medical apparatus as a clinician pushes the needle into a body and so the movement of the sleeve to its retracted position requires

no separate action by the clinician.

After the application of the assembly to a body, on removing the assembly the sleeve moves automatically under the action of the spring to its protecting position, where it wholly overlies that part of the needle projecting beyond the housing and the needle tip. When the sleeve is at its protecting position, the locking member is free of the control member and so can locate between the sleeve and the mount wall of the housing, thereby mechanically blocking movement of the sleeve away from its protecting position.

5

10

15

20

25

Preferably, a part of the control member is located within the sleeve, when the sleeve is in its initial position. The releasable connection may comprise inter-engaged stops on both the outer surface of the control member and the internal surface of the sleeve, which stops will override each other on the application of sufficient axial force thereto. Alternatively, a simple frictional connection may be provided between the sleeve and the control member, whereby the control member will stay at any position within the sleeve unless a sufficient axial force is applied thereto.

In the former case, the spring may act between the control member and an internal flange formed within the tubular locking member and so will act indirectly on the sleeve. In the latter case, the spring may be external to the locking member and act directly on the sleeve.

Preferably, the sleeve is translucent and the control member is of a high visibility material. In this way, the control member can also act as a visual indicator so that a user may readily see whether the assembly has been used and so should be discarded, because the control member will be visible at the forward end of the sleeve. For an arrangement having a

releasable connection with inter-engageable stops, there is the additional benefit of an audible "click" when the control member is moved forwardly by the spring.

In various preferred embodiments, the base of the locking member is circular and has a central hole through which the needle projects. The rearwardly directed face of that base lies at an angle of a few degrees to the true radial plane and is opposed to the rear wall of the housing, which rear wall lies in the true radial plane. The spring is arranged to urge the locking member rearwardly, but so long as the locking member is constrained by the control member or the sleeve to lie co-axial with or extending parallel to the axis of the needle, said rearwardly directed face of the base will not lie flat against the radial rear wall of the housing. Upon release of the locking member, the spring urges the rearwardly directed face of the base to lie flat against the rear wall of the housing, thus inclining the locking member to the axis of the needle and so able to perform its blocking function, to prevent the sleeve moving away from its protecting position.

Advantages possessed by embodiments of the present invention are that they afford wholly aseptic operations, a pre-requisite concerning the introduction of a hollow-bore needle into a body. In preferred embodiments where the initial position and protecting position of the sleeve are one and the same, and so the needle tip is at all times covered other than when the needle is within a body, there is no possibility of the needle being touched accidentally, either by a clinician or by some other component. If the sleeve unintentionally touches some other body to an extent sufficient to expose the needle tip, return of the sleeve to its fully

forward position will lock the sleeve, so preventing use of the needle to perform an injection...

Further, the conventional practice of un-sheathing of a needle by removing a cap is wholly eliminated. It is possible to damage a needle tip by removing a cap and such damage would lead to a more painful injection.

As the needle is covered at all times, other than during body penetration, there is the further advantage of a placebo effect, in that a patient will not see, and so not be frightened by, the needle. Thus, it is possible to give injections even with highly needle-phobic patients.

10

15

20

25

By way of example only, five embodiments of this invention will now be described in detail, with reference to the accompanying drawings, showing the embodiments in various settings. In the drawings:

Figures 1A to 1E show the first embodiment, having an internal spring, with the sleeve moving from an initial position (Figure 1A) to a fully withdrawn position (Figure 1C) and then to a protecting position (Figure 1E);

Figures 1F and 1G are detail views on an enlarged scale of part of the embodiment shown in Figure 1A;

Figures 2A to 2E respectively correspond to Figures 1A to 1E, but of the second embodiment, having an external spring;

Figures 3A to 3D show the embodiment of Figure 2 being used with an adapter in order to prevent the sleeve moving to its protecting position;

Figures 4A to 4D show the third embodiment, also having an external spring, but arranged to be resettable, with the sleeve locked in

the protecting position (Figure 4A) and then being reset, ready for re-use (Figure 4D);

Figures 5A to 5E are similar to Figures 2A to 2E but of a fourth embodiment, having a spring external to the locking member and being used with a syringe;

Figures 6A to 6E are again similar to Figures 2A to 2E but of a fifth embodiment not having a control member; and

Figure 6F is a view on an enlarged scale of part of the embodiment of Figure 6A.

In the following description of the embodiments of this invention, the terms *front*, *forward*, and so on are used to refer to that end of the needle assembly whereat the sharp tip of the needle is located and also to the direction of insertion of the needle, into a body. Conversely, the terms *rear*, *rearwardly* and so on are used to refer to the other end of the needle assembly, to which is connected other equipment such as a syringe or a blood collection system, and also to the direction of removal of a needle, from a body.

Further, like components throughout the various embodiments are given like reference characters and will not be described in detail, for each embodiment.

Figures 1A to 1G

5

10

15

20

25

The first embodiment of needle assembly of this invention shown in Figures 1A to 1G comprises a tubular housing 10 assembled from a rear part 11 and a front part 12, permanently secured together. The rear part 11 includes a tapered socket 13 for receiving the hub of a syringe in the manner of a conventional taper-slip lock, thereby permitting the

part 11 has a boss 14 which carries the mount end of a needle 15, in a manner well known in the art.

The syringe with which the embodiment is to be used may be a pre-filled syringe, such that pre-attachment of the needle assembly immediately renders the syringe ready for use. Rather than the taper slip lock shown, a threaded connector such as a lure lock may be employed. Alternatively, the rear part may be configured for use with known forms of phlebotomy devices for collecting blood.

10

15

25

Slidably mounted in the forward region of the front part 12 is a tubular sleeve 16, the rear end of the sleeve having an external flange 17 which engages a shoulder 18 formed internally within the front part 12. The sleeve is thus constrained against further forward movement from the position shown in Figures 1A and 1E, but may slide rearwardly as shown in Figures 1B and 1C. The forward end 19 of the sleeve 16 has an in-turned lip 20 and the sleeve is of a sufficient length such that when its flange 17 engages shoulder 18, the lip 20 is disposed beyond the sharp tip 21 of the needle.

A tubular locking member 23 surrounds the boss 14 and has a flange 24 at its rear end and disposed adjacent a radial wall 25 of the rear part 11 of the housing. The rearward facing surface of the flange 24 is non-radial with respect to the axis of the locking member and so that face does not lie flat against the radial wall 25, as shown in Figure 1G. The locking member is slightly shorter than the distance between the radial wall 25 and the rear end of the sleeve, when the sleeve is fully forward, as shown in Figure 1A.

A control member 27 is located within the sleeve 16 and has a rear portion 28 which is receivable within the forward part of the locking member 23, the control member being profiled to limit rearward movement thereof into the locking member. A releasable connection is formed between the control member 27 and the internal surface of the sleeve 16, shown in more detail in Figure 1F, whereby the control member is held against movement forwardly within the sleeve 16 until sufficient force is applied to the sleeve in the rearward direction while the control member 27 is held stationary by abutting the forward end of the locking member and the flange 24 of the locking member 23 abuts the rear wall 25 of the housing 10. The releasable connection comprises an internal annular rib 29 engaged with an external preferably segmented annular rib 30 on the control member, or conversely the rib 29 could be segmented and the rib 30 continuous. Sufficient force on the sleeve will break the connection by causing the sleeve rib 29 to ride over the control member rib 30 whereafter the control member may slide freely within the sleeve between the internal face of lip 20 and the sleeve rib 29.

5

10

15

20

25

A helical compression spring 32 is disposed within the locking member 23 and acts between the rear face of the control member 27 and an annular abutment 33 formed within the locking member, just forward of the boss 14. The force exerted by the spring 32 is insufficient to break the connection between the control member and the sleeve when the assembly is in its initial position as shown in Figure 1A. The rearward projection of rear portion 28 of the control member 27 is visible in Figure 1G; this extended projection is intended to support the spring 32 to remain essentially co-axial with the needle.

The operation of the assembly described above will now be described. The initial setting is with the assembly as shown in Figures 1A, 1F and 1G with the sleeve 16 fully forward and wholly protecting the needle 15; the control member 27 is connected to the sleeve and is urged forwardly by the spring 32, transferring the spring force to the sleeve. In this position, flange 17 of the sleeve engages shoulder 18 of the front part 12. The rear portion 28 of the control member is located in the locking member 23, so maintaining that member co-axial with the needle 15.

During initial rearward movement of the sleeve 16, for example by being pressed against a body, the control member is maintained stationary by the locking member 23, in contact with the rear wall 25. If sufficient force is applied to the sleeve 16 to break the connection, the sleeve will slide on to the locking member 23. In addition, the control member is released to move forwardly under the action of the spring, until the control member engages the internal face of the sleeve lip 20. The spring thus continues to urge the sleeve forwardly through the control member, but a force applied rearwardly to the sleeve greater than the spring force will allow continued progress of the sleeve, rearwardly.

Figure 1C shows the sleeve in its extreme rearward position, with the needle 15 projecting to its fullest extent, from the housing 10. Here, the rear portion 28 of the control member has once more entered the locking member and the flange 17 of the sleeve abuts the flange 24 of the locking member. Sufficient reduction on the rearward force on the sleeve (for example, by withdrawing the assembly away from a body) will allow the sleeve to move forwards under the action of the spring, as shown in

20

25

15

Figure 1D. On the sleeve moving to its protecting position shown in Figure 1E, the locking member 23 is free of the sleeve and so moves to the position shown in that Figure, by virtue of the non-radial face of its flange 24 engaging the radial wall 25 of the housing rear part 11, under the action of spring 32. When in its non-axial position, the locking member blocks rearward movement of the sleeve away from its protecting position, so rendering safe the needle the assembly.

5

10

15

20

25

It will be appreciated that in clinical use, as the sleeve 16 comes into contact with the pierceable membrane (e.g. the skin) of a body, the sleeve will automatically move rearwardly from its initial position, allowing penetration of the needle into the body. Further, once the connection between the sleeve and the control member has been broken, the mechanism will automatically lock on the return of the sleeve to the position shown in Figure 1E. Thus, release of the sleeve from the position shown in Figure 1B but before the sleeve has moved to the position shown in Figure 1C will still result in the protecting position of Figure 1E being achieved.

If the assembly is used in conjunction with a syringe to undertake drug draw-up from a phial or ampoule into the syringe, this particular assembly must be discarded and a second assembly fitted to the syringe, to perform an injection. This is in fact the preferred clinical procedure since a lubricated and uncontaminated new needle should be used for body penetration. As well as protecting the needle, the assembly has the advantage of enforcing the "new-needle" clinical procedure, even should a clinician be disinclined to follow the specified procedure.

The control member 27 is preferably made from a highly visible (eg strongly-coloured) plastics material, whereas the sleeve 16 is preferably made of a translucent plastics material. Thus, a simple inspection of the assembly will show whether it has been used, because the control member can be seen at the forward end of the sleeve, or whether it is ready for use, because the control member is not present within that part of the sleeve, beyond the front part 12 of the housing 10 and irrespective of the position of the control member.

Figures 2A to 2E.

10

15

20

25

The second embodiment of Figures 2A to 2E is generally similar to that of Figures 1A to 1E, except that the connection between the control member 27 and the sleeve 16 is differently configured, and a larger spring 35 is employed, external to the locking member 23. The spring acts between the flange 24 of the locking member and the rear face of the sleeve 16, so directly urging the sleeve forwardly, irrespective of the sleeve position with respect to the housing 10.

A simple friction connection is employed between the control member 27 and the sleeve 16, with sufficient friction to ensure the control member remains stationary within the sleeve until sufficient force is applied to the sleeve to overcome that friction. Then, the sleeve will move rearwardly while the control member 27 is held stationary by the locking member and so is advanced relatively, within the sleeve. Subsequently, on forward movement of the sleeve under the action of the spring 35,- the control member moves forward with the sleeve and so comes free of the locking member. Thereafter, this permits the locking

member to perform its locking action as described with reference to Figure 1.

In this second embodiment, the amount of rearward movement of the sleeve needed subsequently to result in the disengagement of the locking member 23 from the control member may be controlled by appropriate selection of the length of the rear portion 28 of the control member 27. With a short rear portion, only small rearward movement of the sleeve will result in an earlier disengagement of the locking member. Conversely, with a long rear portion, a much greater rearward movement of the sleeve is required before subsequent forward movement of the sleeve disengages the control member from the locking member.

5

10

15

20

25

The above action, with a long rear portion 28, may be advantageous where the assembly is to be used to perform drug draw-up from a phial or ampoule, before the same assembly is to be used to perform an injection, where procedures permit the same needle to be used for draw-up and subsequent injection into a body - for example with the delivery of insulin. The sleeve may appropriately be marked to show its maximum movement before locking will occur on subsequent release of the sleeve and provided that movement is not exceeded, then the assembly may be used firstly to undertake drug draw-up and secondly to perform an injection, fully inserting the needle to its correct depth, whereafter the assembly will be rendered safe.

The embodiment of Figure 2 may be employed to give multiple injections, for example if one patient requires a plurality of intradermal injections all in the same general area. This can be achieved by using a tubular adapter 38 as shown in Figure 3, in conjunction with the assembly

of Figure 2 (or Figure 1) together with a syringe 39 having a syringe body 40 and a plunger 41. The needle assembly is fitted to the spigot 42 at the front of the syringe body 40 and the adapter is then slipped over the needle assembly and the syringe body (Figure 3A). The adapter has a nose profile 43 to receive the front of the sleeve 16 and, at its other end, outwardly projecting finger grips 44.

The arrangement of Figure 3 is used by the clinician holding the finger grips 44 together with the head 45 of the plunger 41 and moving the syringe body 40 deeper into the adapter 38, until the sleeve is fully retracted, as shown in Figure 3D. So long as pressure is maintained between the finger grips 44 and the plunger head 45, the adapter 38 will hold the sleeve 16 in its retracted position. An increased force will be required to drive the plunger 41 into the syringe 39 to deliver a drug into the body. A reduction in that increased force should maintain the sleeve in its retracted position, so allowing the re-siting of the needle to another part of the body, for further injections. On releasing all pressure, spring 32 will move the sleeve 16 forwardly so fully protecting the needle before the syringe is removed from the adapter 38.

Figure 4A to 4D.

5

10

15

20

25

This embodiment is a modified form of the second embodiment shown in Figures 2A to 2E. The modification is solely to the control member, which is differently profiled as shown in Figure 4A. The control member 50 is provided with a counter-bore 51 at its forward end and the rear portion 52 tapers towards its free end. Such a control member 50 allows resetting of the assembly to a ready-to-use condition, from a locked condition.

Figure 4A shows the assembly in its protecting (locked) condition, this corresponding to the setting of Figure 2E. The mechanism may be reset by means of a tool having a fine tubular shaft 53, receivable through the lip 20 of the sleeve 16 and into the counter-bore 51 of control member 50. Using this tool, the control member 50 may be pushed rearwardly, overcoming the friction between the control member 50 and the sleeve 16, until the control member re-enters the locking member 23. The tapered profile of the rear portion 52 lifts the control member out of its locking position (Figure 4B) and continued rearward movement of the control member will bring the locking member co-axial with the needle, as shown in Figure 4C. Removal of the shaft 53 leaves the assembly reset, ready for use.

There is no risk to a clinician in using the tool to reset the mechanism. There is no access to the needle tip until the shaft 53 has been used to complete the resetting; during insertion of the shaft, the sleeve protects the needle and no manual access can be gained to the needle tip.

Figures 5A to 5E

5

10

15

20

25

A fourth embodiment of this invention is shown in Figures 5A to 5E. This embodiment has a support wall 55 provided with a socket 56 to permit the assembly to be mounted on the hub 57 of a conventional syringe 58, the hub and socket together forming a conventional taper slip lock. A conventional lure lock could be used, instead. The syringe has a cylindrical body 59 within which is mounted a plunger 60, to permit charging of the syringe and discharging of a drug, through a needle 15 supported on wall 55. A sleeve 62 has a forward portion 63

corresponding to sleeve 16 of the previous embodiments and a rearward portion 64 formed integrally with the forward portion 63. The rearward portion has a sufficient diameter to fit over the cylindrical body 59 of the syringe and is provided with an annular bead 65 at its free end, to stop the sleeve 62 coming off the wall 55.

Internally, the arrangement is essentially the same as that of the embodiment of Figure 2, and so includes a locking member 23, a control member 27 and a spring 35 external of the locking member. The control member 27 is a frictional fit within the forward portion 63 of the sleeve 62 and so may be slid forwardly within the forward portion, as the sleeve 62 is moved rearwardly. As previously, sufficient forward movement of the control member within the forward portion 63 allows the locking member 23 to move to its inclined position shown in Figure 5E once the sleeve 62 has moved to its protecting position, so thereafter preventing retracting movement of the sleeve.

Figures 6A to 6F

5

10

15

20

25

The fifth embodiment is shown in Figures 6A to 6F. This does not include a control member, but otherwise is similar to the second embodiment, shown in Figures 2A to 2E. In this fifth embodiment, at least one stop 70 is formed internally within the rear part 11 of the housing 10, adjacent but spaced from the inner face of the radial wall 25. In addition, the sleeve 71, though generally similar to sleeve 16, has a shoulder 72 part way therealong, for engaging the locking member 23 once the sleeve has been moved sufficiently, rearwardly.

The or each such stop 70 is appropriately configured to hold the locking member 23 away from the radial wall 25. The locking member 23

has such a length that when it bears on the stops 70 and the sleeve 71 is in its initial position, the locking member is located within the rear end of the sleeve 71, as shown in Figure 5A. In this position, the force exerted by the spring 35 is insufficient to move the flange 24 of the locking member over the or each stop 70.

5

10

15

On moving the sleeve rearwardly, the shoulder 72 of the sleeve will abut the forward end of the locking member 23. Thereafter, sufficient pressure on the sleeve will press the flange 24 of the locking member 23 over the stops 70, to engage the radial wall 25 of the housing rear part 11.

From this point, operation is as with the second embodiment of Figure 2. Movement of the assembly away from a body allows the sleeve 71 to move forwardly under the action of the spring 35, and when fully forward, the locking member 23 is inclined to the needle axis by virtue of the inter-engagement of the non-radial flange 24 of the locking member with the radial face of wall 25. The locking member thus blocks subsequent movement of the sleeve 71, towards its retracted position.

CLAIMS

1. A medical needle assembly comprising:

10

15

20

- a needle having a mount end and a sharp tip;
- a support wall carrying the mount end of a needle so as to project away therefrom;
 - a sleeve mounted on the support wall and being slidable with respect thereto from an initial position where the sleeve covers at least the greater part of the projecting needle to a retracted position where the tip of the needle is exposed along with a part of the needle extending back from the tip, and then to a protecting position where the sleeve covers the needle tip and at least part of the needle projecting back from its tip;
 - a spring arranged to urge the sleeve away from the support wall;
 - a locking member projecting forwardly from the support wall, the locking member being movable between a free position where the locking member extends generally parallel to the needle axis and the sleeve may slide to its withdrawn position and a blocking position where the locking member is disposed between the support wall and the sleeve and is offaxis with respect to the needle axis, thereby blocking movement of the sleeve away from its initial position; and
 - control means which holds the locking member in its free position until tripped by movement of the sleeve away from its initial position, the control means thereafter permitting the locking member to move to its blocking position on movement of the sleeve to its protecting position, so

preventing subsequent movement of the sleeve away from its protecting position.

2. A medical needle assembly as claimed in claim 1, wherein the support wall defines a connector for a cylindrical body to extend co-axially with the needle, and when connected to a tubular body the sleeve is slidably supported thereby.

5

15

20

- 3. A medical needle assembly as claimed in claim 1, wherein the support wall is defined by a rear wall of a tubular housing which slidably carries the sleeve.
- 4. A medical needle assembly as claimed in claim 2 or claim 3, wherein the control means includes a releasable connection between two components relatively movable along the needle axis.
 - 5. A medical needle assembly as claimed in claim 4, wherein the said components comprise the housing and the locking member, movement of the sleeve towards its retracted position releasing the connection to permit the locking member to move towards the rear wall of the housing.
 - 6. A medical needle assembly as claimed in claim 4, wherein the said components comprise the sleeve and a control member received within the rear end of the sleeve and movable towards the front end thereof on release of the releasable connection.
 - 7. An assembly for supporting a medical needle having a mount end and a tip, which assembly comprises:
 - a tubular housing having a rear wall provided with an internal mount portion adapted to support the mount end of a needle, the housing being open at its opposed end so that a supported needle may extend from the mount portion and project out of the opposed end;

— a sleeve slidably mounted within the housing to surround a supported needle, the sleeve being slideable with respect to the housing from an initial position where the sleeve will cover at least the greater part of a supported needle projecting from the housing to a retracted position exposing the tip and part of a supported needle extending back from the tip, and then to a protecting position where the sleeve covers that part of the needle projecting beyond the housing including the needle tip, the sleeve having a rear end nearer the rear wall of the housing and there being means to prevent the sleeve sliding off the housing;

– a locking member provided within the housing, the locking member having a base disposed between the rear end of the sleeve and the rear wall of the housing and a locking section which extends from the base generally parallel to the length of the sleeve and co-operable with the sleeve;

- a control member also receivable within the sleeve and which initially supports the locking section of the locking member to lie substantially parallel to the sleeve axis, there being a releasable connection between the sleeve and the control member; and
- a spring disposed to urge apart the sleeve and the locking
 member;

in which assembly:

10

15

- with the sleeve in its initial position the control member is disposed adjacent the rear end of the sleeve, engaged with the locking section of the locking member;
- on movement of the sleeve to its retracted position the control
 member releasable connection is released so permitting the

control member to move into the sleeve, the control member guiding the locking section into the sleeve; and

on the sleeve subsequently moving to its protecting position under the action of the spring, the base of the locking member is urged to bear on the housing rear wall and the locking section of the locking member engages behind the rear end of the sleeve, so preventing subsequent retraction of the sleeve from its protecting position.

5

- 8. An assembly as claimed in claim 7, wherein the sleeve has an external annular rib at or adjacent the rear end thereof and the housing defines an internal abutment engageable by the rib on the sleeve to prevent the sleeve coming free of the housing.
 - 9. An assembly as claimed in claim 7 or claim 8, wherein the control member is located partly within the sleeve when the latter is in its initial position.
 - 10. An assembly as claimed in claim 9, wherein the releasable connection is formed directly between the outer surface of the control member and the internal surface of the sleeve.
- 11. An assembly as claimed in claim 10, wherein the releasable connection comprises inter-engaged stops on both the outer surface of the control member and the internal surface of the sleeve, which stops will over-ride each other on the application of a sufficient axial force thereto.
- 12. An assembly as claimed in claim 10, wherein the locking section of the locking member is of tubular form, and the spring acts between the

control member and an internal flange formed within the tubular locking section and so indirectly on the sleeve through the releasable connection.

13. An assembly as claimed in claim 12, wherein the sleeve is formed with an internal stop at its forward end, the control member is a free sliding fit within the sleeve, and when the releasable connection is released, the control member moves under the action of the spring into engagement with the internal stop.

5

- 14. An assembly as claimed in claim 9, wherein the releasable connection is formed by the control member fitting in the sleeve in a frictionally-engaging manner.
- 15. An assembly as claimed in claim 14, wherein the locking section of the locking member is of tubular form and the spring surrounds the locking section to act directly between the rear end of the sleeve and the base of the locking member.
- 16. An assembly as claimed in claim 14 or claim 15, wherein the control member includes an axial projection which is received in the tubular locking section of the locking member and is withdrawn therefrom by movement of the sleeve towards the needle tip, drawing the control member therewith.
- 20 17. An assembly as claimed in claim 16, wherein the length of the axial projection is selected to control the maximum permissible movement of the sleeve towards the retracted position before subsequent movement of the sleeve in the opposite direction locks the sleeve against movement towards a retracted position.
- 18. An assembly as claimed in claim 16 or claim 17, wherein the forward end of the control member has a counter-bore and the axial

projection is tapered to permit the re-entry of that axial projection into the locking member, by pressure applied to the control member by means of a tool engaged with said counter-bore.

19. An assembly as claimed in any of claims 7 to 18, wherein the spring is a helical compression spring.

5

10

15

20

- 20. An assembly as claimed in any of claims 7 to 18, wherein the base of the locking member has a central hole through which a supported needle will extend.
- 21. An assembly as claimed in claim 20, wherein the base of the locking member co-operates with an internal housing wall portion when the locking member comes free of the sleeve upon the latter moving to its protecting position, so that a turning moment is applied to the locking member about an axis transverse to the length of the sleeve, moving the end of the locking section remote from the base to block retracting movement of the sleeve.
 - 22. An assembly as claimed in claim 21, wherein one of the base and said internal housing wall portion has an off-set boss projecting towards the other of the base and said internal housing wall portion, whereby on the base being urged towards the internal housing wall portion, the off-set projection applies said turning moment to the locking member.
 - 23. An assembly as claimed in claim 21, wherein one of the base and said internal housing wall portion has a non-radial face opposed to the other of the base and said internal housing wall portion, whereby on the base being urged towards the internal housing wall portion, the non-radial face applies said turning moment to the locking member.

- 24. An assembly as claimed in any of claims 7 to 23, wherein the sleeve when in its initial position is in the same position relative to the housing as when in its protecting position.
- 25. An assembly as claimed in any of claims 7 to 24, wherein each of the housing, the sleeve, the control member and the locking section of the control member has a generally annular regular cross-sectional shape.
 - 26. An assembly as claimed in any of claims 7 to 25, wherein the sleeve is translucent and the control member is of a high-visibility material, whereby the presence of the control member at the front end of the sleeve can be seen through the sleeve wall.

10

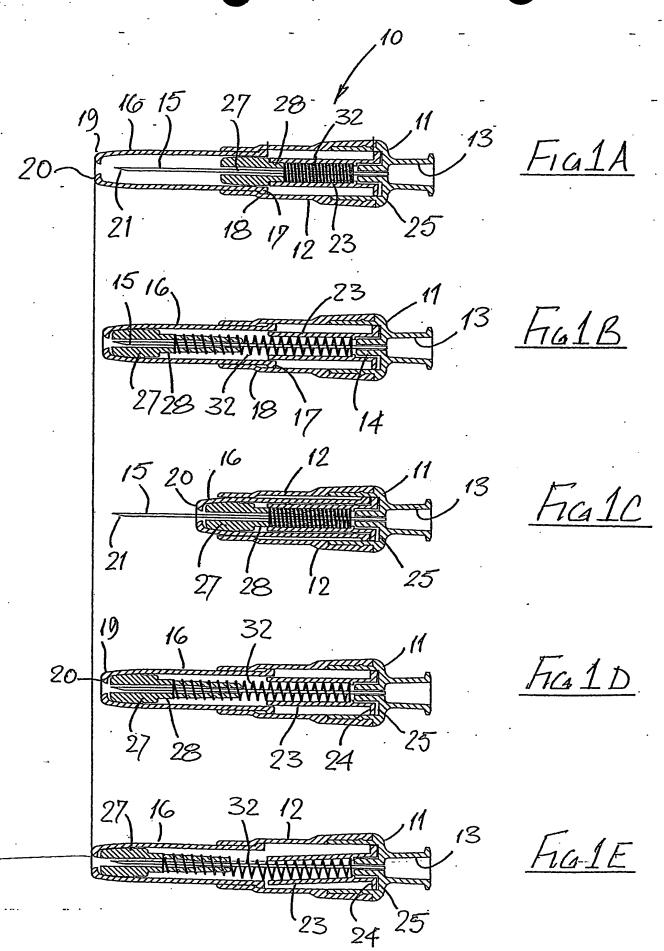
- 27. An assembly as claimed in any of claims 7 to 11, wherein the locking section of the locking member is in the form of a bar or an arm projecting from the base.
- 15 28. An assembly as claimed in any of claims 7 to 27, wherein the housing is provided an external connector for apparatus with which the assembly is to be used, which connector communicates with the mount portion of the housing.
- 29. An assembly as claimed in claim 28, wherein the connector comprises a conical socket for receiving a correspondingly-shaped spigot provided on apparatus with which the needle assembly is to be used.
 - 30. An assembly as claimed in any of claims 7 to 29, in combination with a medical needle supported by the mount portion of the housing, to extend-from that mount portion through and beyond the housing, the needle also extending through the locking member, the control member and the sleeve.

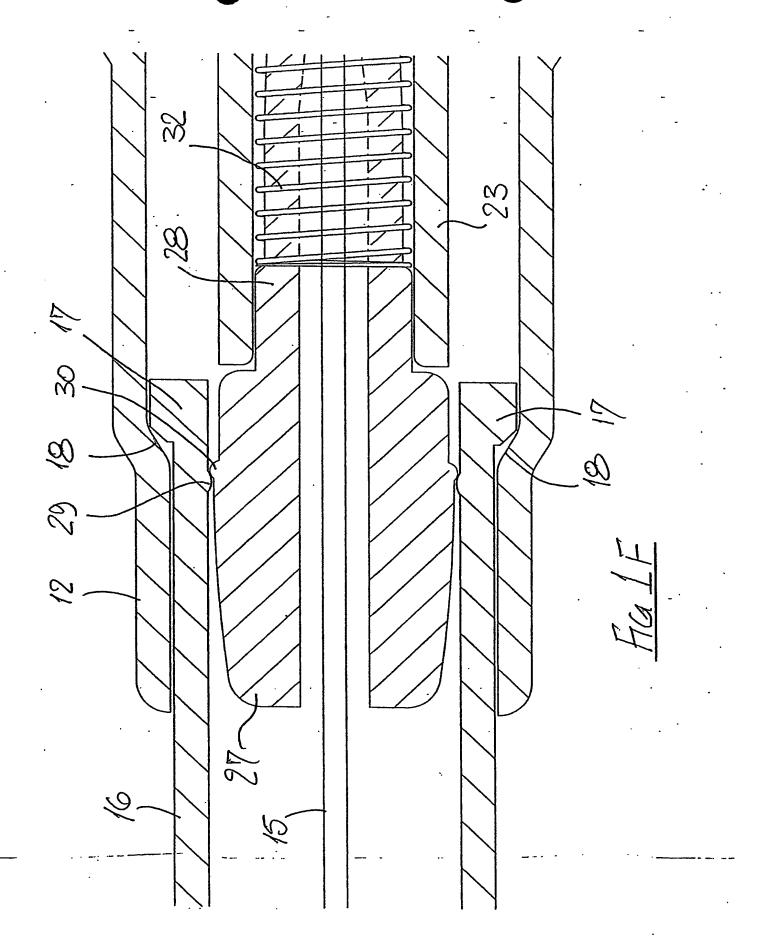
31. An assembly as claimed in claim 30, in combination with an adapter within which the housing is receivable and having a front end for restraining the forward end of the sleeve of the assembly, to permit the needle to project from the sleeve and the adapter whilst restraining the sleeve within the assembly from moving to its protecting position.

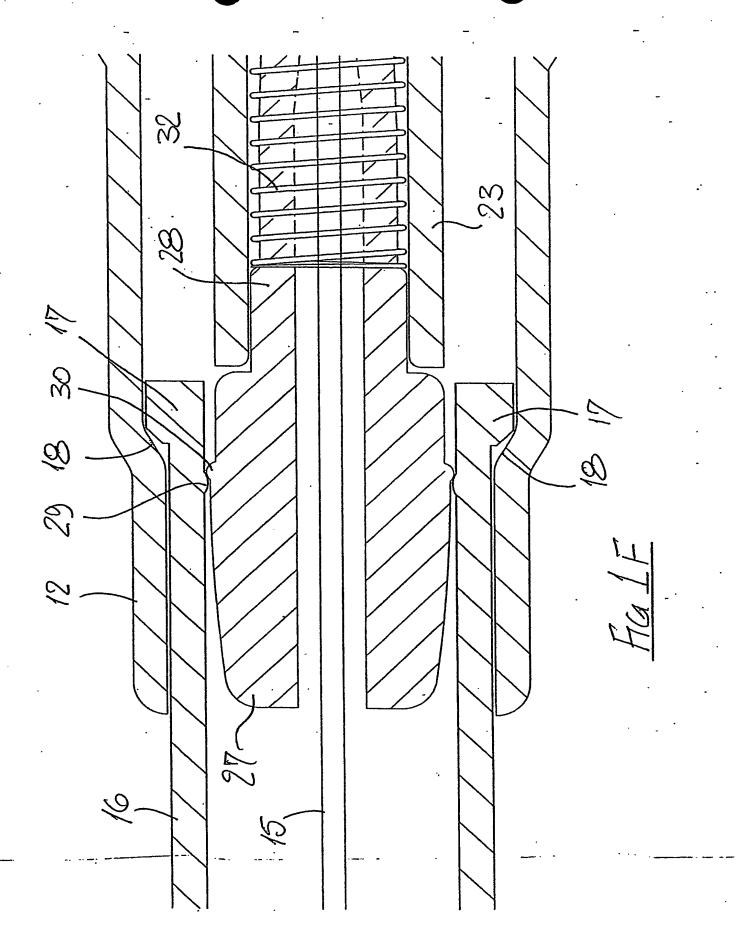
5

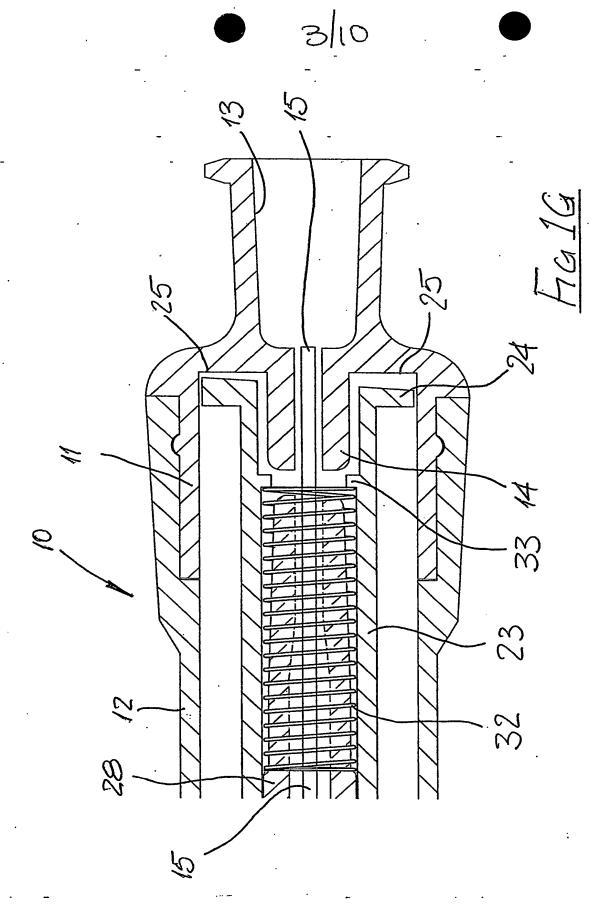
10

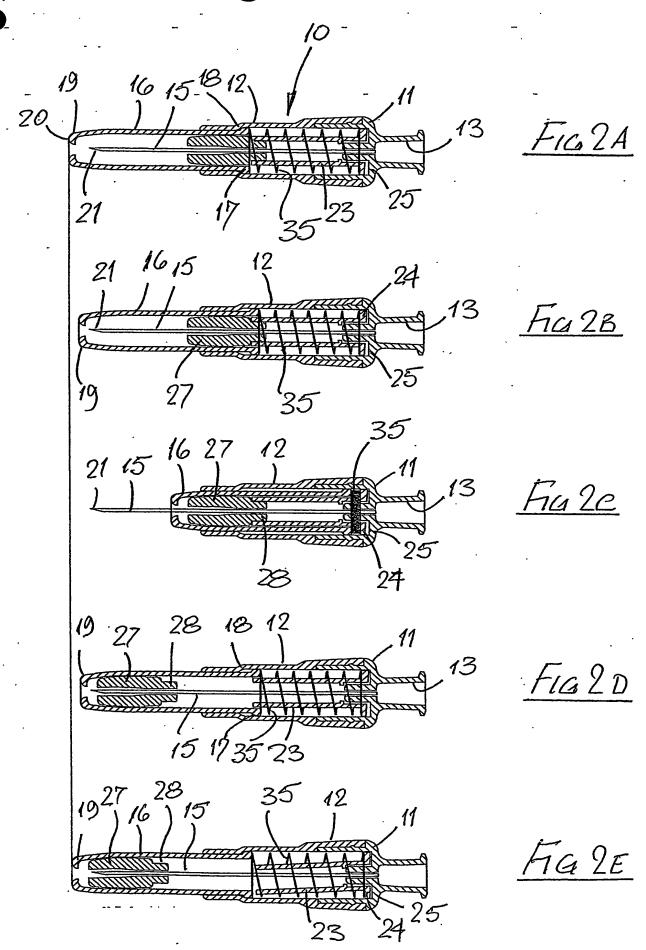
32. An medical needle assembly as claimed in claim 1 and substantially as hereinbefore described, with reference to and as illustrated in Figures 1A to 1G or in Figures 2A to 2E or in Figures 3A to 3D or in Figures 4A to 4D or in Figures 5A to 5E or in Figures 6A to 6F of the accompanying drawings.

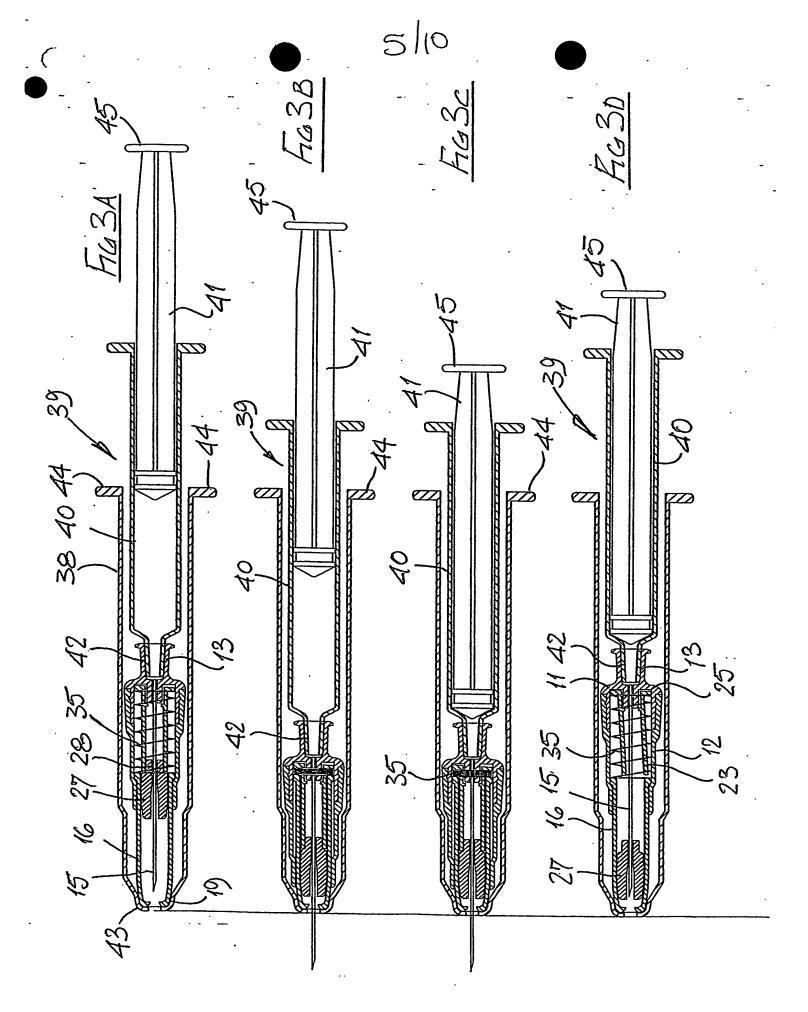


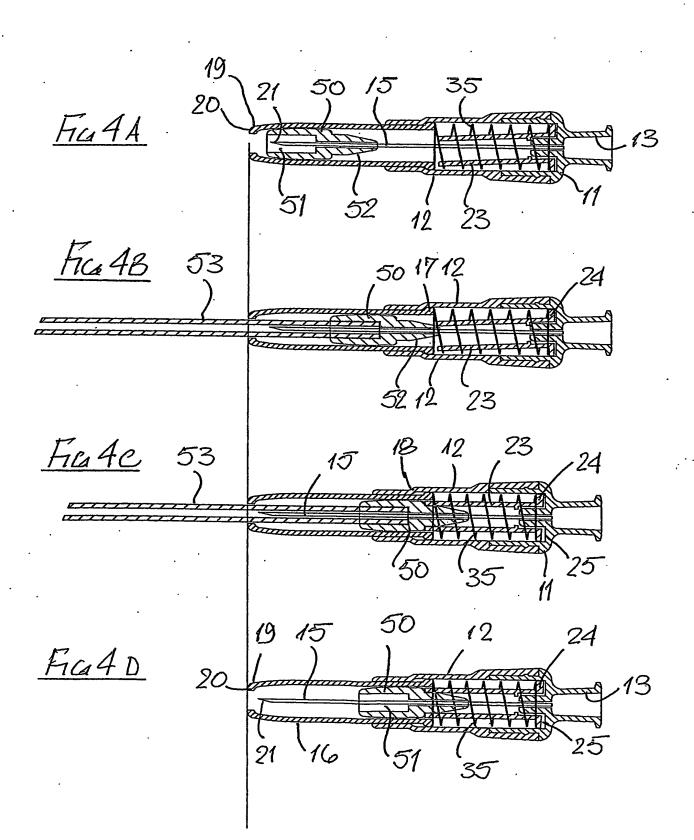


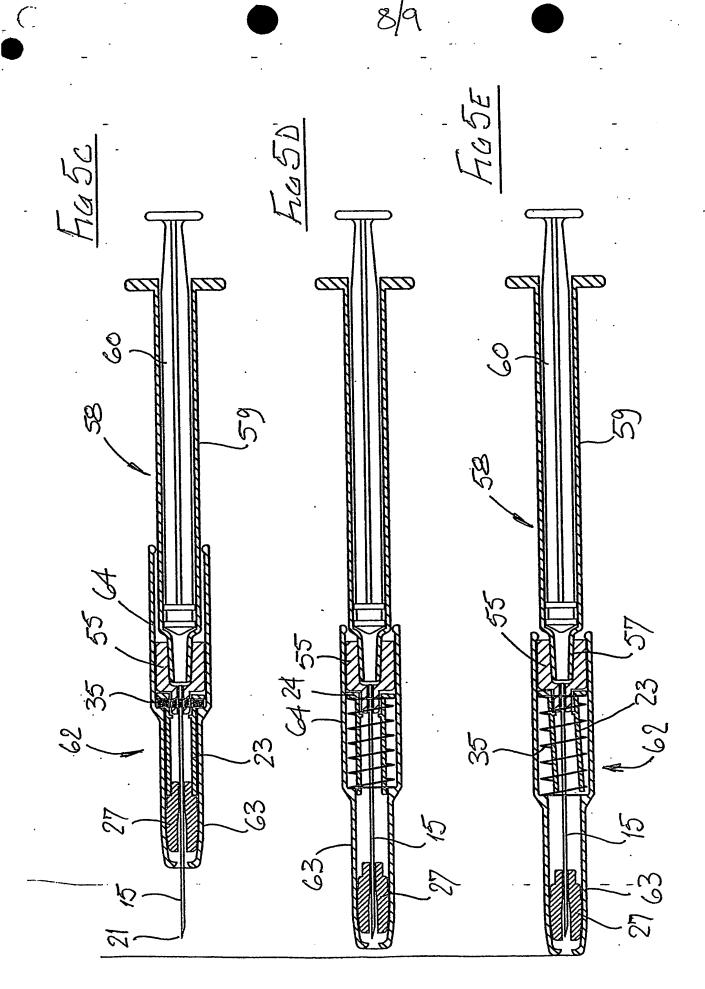


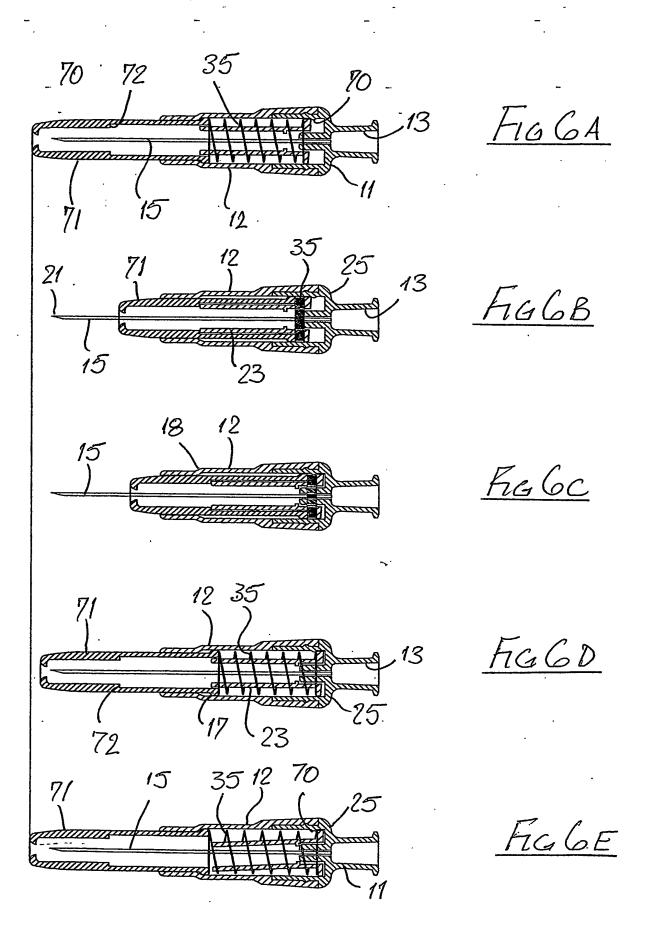


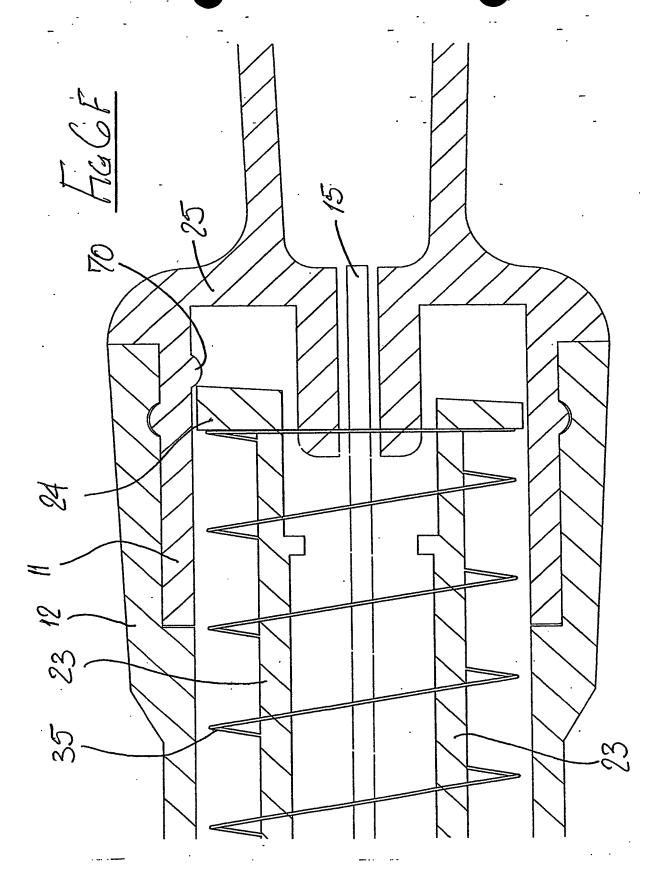












· ···· ·

This Page Blank (usp*

THE PATENT OFFICE
16 JUL 2003
Received in Patents